Personal Data Privacy Not a Concern for Vast Majority of Clinical Trial Subjects, Study Finds

By William Myers

Patients overwhelmingly feel that the benefits of clinical trials outweigh the risks to their personal privacy, according to a new study in the New England Journal of Medicine.

A trio of researchers at Stanford's medical school surveyed 771 people who had either enrolled in clinical trials or whose children had enrolled in trials. The researchers asked a series of questions gauging their levels of concern over patients’ data privacy. Statements included, “It could be harder to get people to agree to be in clinical trials if they know their data will be shared” and “It could be embarrassing if the information was linked back to me.”

Fewer than 8 percent of the respondents said that the potential harms of data breaches outweighed the benefits of participating in trials, 82 percent said the benefits outweighed any risks and 10 percent called it even. In fact, respondents “were more concerned that data sharing could deter people from enrolling in clinical trials (37 percent), that companies might use the information for marketing purposes (34 percent) or that their data could be stolen (30 percent),” lead researcher Michelle M. Mello wrote for her colleagues.

More than that, “strong majorities” of respondents “believed that data sharing would yield ‘a great deal’ or ‘a lot’ of several benefits,” Mello wrote.

see Data Privacy on page 3 »

Evolution of eConsent Technology Leads to Greater Adoption from Sponsors and Clinical Trials Sites

By Suz Redfearn

eConsent has developed a reputation for being the next big technological innovation in clinical trials, and adoption efforts are accelerating.

Numerous industry surveys have shown that most of the top Pharma companies are engaged or planning an eConsent initiative in the near future, with many of them already having an eConsent strategy in place.

Technology advances have made eConsent implementation much easier. For example, newer SaaS-based applications that leverage integration with the IRB review now can be implemented rapidly, and at a much lower cost.

Sponsors who love their paper-based processes have complained that solutions like eConsent are too expensive, but the cost of adding eConsent to a study is more than recouped through enhanced study start-up time, reduced monitoring visits, and better subject retention.

All the same, many sponsor efforts are still in pilot phase, said Neetu Pundir, who manages product strategy for CRF Health’s electronic consent offering, TrialConsent.

“This industry is very conservative and cautious, and a lot of organizations have wanted to do a pilot before rolling this out,” said Pundir. “But as sponsors of all sizes and types are beginning to finish their pilots

see eConsent Technology on page 4 »
Effective Date for Medical Device Clinical Trials Rules Included in HHS Regulatory Agenda

HHS will publish its semi-annual regulatory agenda on Monday, and it includes a February 21, 2019, effective date for a new rule that will require that data from medical device studies conducted outside the U.S. be gathered in accordance with good clinical practices, including review and approval from an independent ethics committee and well-documented informed consent. The agency’s final rule applies to data intended to support IDE applications, 510(k) submissions, and de novo classification requests, as well as applications for premarket approval, product development protocols and humanitarian device exemptions. It also applies to bench and in vitro diagnostic studies of de-identified specimens. The new mandates would replace the current pre-market approval regulations that require clinical studies to conform to the Declaration of Helsinki or the law of the country where the research is conducted, whichever carries greater protection for human subjects, the FDA said. The rule does not apply to all clinical investigations performed overseas, but only sets criteria for FDA acceptance of data used to support device marketing applications or submissions.

NICE’s Service for New Product Economic Model Review Wins First Endorsement

UK regulators have won their first endorsement for their new peer-reviewed service designed to help clinical researchers put together more thorough studies for drugs, devices, diagnostics and treatments. The National Institute for Health and Care Excellence launched what it called PRIMA — Preliminary Independent Model Advice — as a service last December. It’s designed to help researchers “ensure the quality of their model structure, coding, usability and transparency,” On Thursday, regulators announce that drug company Takeda had endorsed the service, after completing two PRIMA projects. “We appreciated the PRIMA team’s engaging and flexible approach at this pivotal stage in development and look forward to using the service as part of our model development going forward,” the company said in a news release. Takeda was one of the first companies to test PRIMA.

Market Pressures, IP Rights Depriving Public of Key Data, Group Claims

Results from nearly 40 percent of clinical trials for Crohn’s Disease remain publicly unavailable — further proof that market pressures are depriving the public of important health data, a public advocacy group is claiming. The Center for Economic and Policy Research, a Washington, DC-based think tank, wanted to get a handle on whether drug companies’ intellectual property rights was in conflict with the public’s right to know about safety. The group selected Crohn’s Disease as the lens to which the view the problem. Researchers found that of the 53 trials published at the FDA’s ClinicalTrials.gov site, only 32 had led to published journal pieces as of January, 2018. Of those trials that had led to published pieces, there were still information gaps. “The other studies did not indicate, for example, whether the treatment was more effective for men than women or for younger people than older people,” the center said in announcing its findings. “The lack of transparency surrounding drug safety and efficacy data is an enormous loss to potential users of data, either clinicians or other investigators,” the group said. “As a policy matter, the government could require full disclosure of test results for any study receiving any form of government funding.” You can read the group’s full report here: http://www.fdanews.com/ext/resources/files/2018/06-08-18-CEPR.pdf?1528468800.

Clinical Trials Should Focus on Organoids, Study Group Urges

Clinical trial funding should focus on human-based methods, such as organoids, in order to help improve the world’s drug pipeline, a panel of researchers and trial experts has agreed. Representatives from the Humane Society, the National Institutes of Health, the FDA and others who met at the BioMed21 Collaboration workshop also agreed that incentives should be realigned so that researchers are rewarded for standardizing and sharing data and “consistent ontology.” Also, researchers have to improve interoperability amongst communications and other technologies so that research can benefit from “improved interdisciplinary and international collaboration,” the group said in a report published in the latest edition of Drug Discovery Today. The workshop was held to help focus on what organizers called “human-relevant research.” More than 90 percent of drug candidates entering clinical trials will not be approved by regulators, organizers said. “Without significant intervention, the pipeline responsible for new drug production is predicted to dry up completely within 50 years,” the group said.
Data Privacy (continued from page 1)

“When respondents were asked to choose the most important benefit of data sharing, the most popular choices were making sure people’s participation in clinical trials leads to the most scientific benefit possible (18 percent) and helping to get answers to scientific questions faster (17 percent),” the study says.

“Their willingness to share was high regardless of the way in which the data would be used, with the exception of litigation, and it extended to uses that involved no prospect of direct benefit to themselves or their family members,” Mello wrote.

The study is consistent with years of data that patients and parents in clinical trials are grateful for the chance to participate. There were even some paradoxical results. “Despite low levels of trust in pharmaceutical companies,” Mello wrote, “most trial participants were willing to share their data with them.”

The positive vibes may be attributable in part to the fact that so few people are able to participate in clinical trials, Mello and her colleagues speculated.

“Clinical trial participants typically constitute a small proportion of the people who are eligible for participation and may represent those who are least bothered by data sharing and most enthusiastic about contributing to science. Their familiarity with physician-researchers may impart especially high trust in research and researchers. Indeed, nearly all of our respondents reported very positive experiences as trial participants,” Mello wrote.

FDA Plans to Reorganize CDER around Multi-disciplinary Teams and to Streamline Reviews of New Drug Applications

By William Myers

A new reorganization at the FDA’s Center for Drug Evaluation and Research will assign multidisciplinary teams to work on new drug applications from the beginning of the regulatory process, will centralize project management under the Office of New Drugs, and increase the number of offices overseeing review divisions from five to nine and increasing the overall number of review divisions from 19 to 30, the agency announced June 4.

“These changes are intended to free up resources so that our scientists and physicians have more time to focus on drug development, particularly for unmet medical needs, and on the multiple collaborations needed to make sure candidate drugs are developed and assessed properly, with appropriate input from external scientists, expert physicians and patient communities,” said Janet Woodcock, CDER director, in a blog posted to the agency’s web site.

“As always, our goals are to expand access to safe and effective new drug therapies, conduct efficient and comprehensive safety surveillance and ensure that accurate information about those drugs is available,” Woodcock said.

“One principal aim of these proposed changes is to elevate the role of our scientists and medical officers to take on even more thought leadership in their fields.”

—Scott Gottlieb, commissioner, FDA

The reorganization adds even more to Woodcock’s portfolio. In addition to running CDER, Woodcock is also director of the Office of New Drugs. Her reorganizational proposals come as the agency struggles to meet the deadlines laid out in the 21st Century Cures Act.

“It could be that they see it as a way to help address the rollout and implementation in a more effective way,” said Julie Tibbets, a partner at Goodwin, Procter who focuses her law practice on drug regulation and policy. “That said, I think that’s a tall order that they’ve laid out for themselves.”

According to the FDA’s own web site, the Cures Act lays out some 30 “deliverables” for CDER; CDER has completed three of them.

“They keep a chart of the deliverables for the Cures Act,” Tibbets added.”They’re not tracking very well on this.”

Woodcock’s blog post was followed directly by a statement of enthusiastic support from FDA Commissioner Scott Gottlieb.

“One principal aim of these proposed changes is to elevate the role of our scientists and medical officers to take on even more thought leadership in their fields,” Gottlieb said. “We want to give our clinicians and scientists more time, better tools and greater support to advance the clinical and regulatory principles that the FDA uses to evaluate new drugs for safety and efficacy.”

In 2017, the FDA approved 46 novel drugs “100 percent of which were reviewed on time,” Woodcock’s blog says.

“Our new plan is designed to help us generate efficiencies so we can build stronger external collaboration capabilities and enhanced support for the scientific, clinical and technological innovation necessary for new drug therapies,” Woodcock said.

Tibbets said she remains skeptical. “I mean guidance documents take time. I think that this is un-realistic,” she said.
now, we’re seeing them go right into adoption.”

Pundir says she’s seeing a paradigm shift as sponsors now move away from using paper processes in one of the last areas where they had clung to paper. Now, she says, there may be a bit more of a delay as sponsors formalize their efforts around eConsent, adding staff familiar with eConsent, or training staff they already have. But for the most part, she said, their resistance to it is gone.

The fact that it took so long for sponsors to accept it hasn’t surprised Susan Vallow, vice president of Electronic Clinical Outcome Assessments (eCOA) Solutions for MedAvante-ProPhase, who has worked in eCOA for 20 years, and watched it take almost that long for sponsors to get comfortable with paperless processes in other realms of clinical research, like clinical report forms.

“This industry is very conservative and cautious, and a lot of organizations have wanted to do a pilot before rolling this out. But as sponsors of all sizes and types are beginning to finish their pilots now, we’re seeing them go right into adoption.”

—Neetu Pundir, manager of product strategy, CRF Health

Sites also are more open to adopting eConsent now, as the technology behind it has gotten more streamlined, and is easier to use, as opposed to just another complicated thing sponsors want sites to come up to speed on.

Plus, the new eConsent solutions also have version control imbedded in them, said Vallow, so sites no longer have to hunt around for the multiple versions of an eConsent document. Instead, all versions are accessible, having been tracked electronically.

So what’s keeping all sponsors from adopting eConsent? Some countries, including China and Germany, don’t allow eSignatures, which are a key part of eConsent. Many other countries have laws around eSignatures that are vague enough to spook sponsors.

With virtual trials — otherwise known as direct-to-patient trials — beginning to enter the marketplace, eConsent will only become more prominent.
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## Drug & Device Pipeline News

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
</tr>
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<tbody>
<tr>
<td>Peloton Therapeutics, Inc.</td>
<td>PT2977 (oral HIF-2α inhibitor)</td>
<td>Treatment of von Hippel-Lindau (VHL) disease-associated kidney cancer</td>
<td>Phase II trial initiated enrolling 50 subjects in the U.S.</td>
<td>pelotontherapeutics.com</td>
</tr>
<tr>
<td>Viking Therapeutics, Inc.</td>
<td>VK2809</td>
<td>Primary hypercholesterolemia and non-alcoholic fatty liver disease (NAFLD)</td>
<td>Phase II trial initiated</td>
<td>vikingtherapeutics.com</td>
</tr>
<tr>
<td>Tricida, Inc.</td>
<td>TRCA-301</td>
<td>Chronic kidney disease patients with metabolic acidosis</td>
<td>Phase III trial initiated enrolling 217 subjects in the U.S. and Europe</td>
<td>tricida.com</td>
</tr>
<tr>
<td>Janssen (part of Johnson &amp; Johnson)</td>
<td>Esketamine nasal spray</td>
<td>Adults with treatment-resistant depression</td>
<td>Phase III trial initiated</td>
<td>janssen.com</td>
</tr>
<tr>
<td>Camber Spine Technologies</td>
<td>ENZA (Titanium Anterior Lumbar Interbody Fusion (ALIF) system)</td>
<td>Autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1</td>
<td>510(k) clearance granted by the FDA</td>
<td>cambermedtech.com</td>
</tr>
<tr>
<td>Royal Philips</td>
<td>Ingenia Elition 3.0T MR solution</td>
<td>Increased diagnostic performance</td>
<td>510(k) clearance granted by the FDA</td>
<td>philips.com</td>
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<tr>
<td>Partner Therapeutics, Inc.</td>
<td>Leukine</td>
<td>Adult and pediatric patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)</td>
<td>Approval granted by the FDA</td>
<td>partnertx.com</td>
</tr>
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<td>Mylan</td>
<td>Fulphila (pegfilgrastim-jmbd)</td>
<td>Febrile neutropenia</td>
<td>Approval granted by the FDA</td>
<td>mylan.com</td>
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<tr>
<td>Eli Lilly and Incyte Corporation</td>
<td>OLUMIANT (baricitinib)</td>
<td>Adults with moderately-to-severely active Rheumatoid Arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) inhibitor therapies</td>
<td>Approval granted by the FDA</td>
<td>lilly.com</td>
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<td>Micronics, Inc.</td>
<td>PanNAT STEC Test</td>
<td>Shiga toxin-producing E. Coli (STEC)</td>
<td>Clearance granted by the FDA</td>
<td>micronicsinc.com</td>
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<td>Chugai Pharmaceutical Co., Ltd.</td>
<td>HEMLIBRA (U.S. generic name: emicizumab-kxwh)</td>
<td>Adults and children with hemophilia A without factor VIII inhibitors</td>
<td>Priority Review Designation granted by the FDA</td>
<td>chugai-pharm.co.jp/english</td>
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<tr>
<td>Pfizer</td>
<td>Talazoparib</td>
<td>Germline (inherited) BRCA-mutated (gBRCAm), HER2-negative locally advanced or metastatic breast cancer (MBC)</td>
<td>Priority Review Designation granted by the FDA</td>
<td>pfizer.com</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Xalkori (crizotinib)</td>
<td>Relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK)-positive</td>
<td>Breakthrough Therapy Designation granted by the FDA</td>
<td>pfizer.com</td>
</tr>
<tr>
<td>AutoGenomics, Inc.</td>
<td>INFINITI Neutral Response Panel</td>
<td>Opioid dependency</td>
<td>Breakthrough Device Designation granted by the FDA</td>
<td>autogenomics.com</td>
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<tr>
<td>Curis, Inc.</td>
<td>Fimepinostat (CUDC-907)</td>
<td>Relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL)</td>
<td>Fast Track Designation granted by the FDA</td>
<td>curis.com</td>
</tr>
<tr>
<td>Alnylam Pharmaceuticals, Inc.</td>
<td>ALN-TTRsc02</td>
<td>Transthyretin-mediated amyloidosis</td>
<td>Orphan Drug Designation granted by the FDA</td>
<td>alnylam.com</td>
</tr>
</tbody>
</table>

For news on trial results, FDA approvals and drugs in development, Join the LinkedIn Drug Research Updates group!
**Trial Results**

**Cellerant Therapeutics Presents Results for CLT-008**

Cellerant Therapeutics announced results from a randomized controlled Phase II clinical trial of CLT-008 (romylocel-L, human myeloid progenitor cells), a universal, off-the-shelf cell therapy intended to prevent infections during neutropenia. The Phase II trial was conducted in patients newly diagnosed with acute myeloid leukemia (AML) who underwent induction chemotherapy. Key results of the Phase II study showed that CLT-008 significantly reduced the incidence of serious infections, the number of days in hospital and the use of antimicrobial drugs compared to control. The Phase II study was conducted in patients aged 55 years or older who received either “7+3” (cytoreduction) or “HiDAC” (high-dose cytarabine) induction chemotherapy. A total of 163 patients were enrolled and randomized 1:1 to receive either CLT-008 plus granulocyte colony stimulating factor (G-CSF) (the treated group) or G-CSF alone (the control group). CLT-008 was administered to the treated group approximately nine days after initiation of induction chemotherapy (Day 9), and G-CSF was administered to both groups approximately 14 days after initiation of chemotherapy (Day 14). The study results showed the incidence of serious infection was 76 percent less in the treated group compared to the control group (one sided p = 0.001).

**AbbVie’s Upadacitinib Monotherapy Meets Primary and Secondary Endpoints**

AbbVie announced positive top-line results from SELECT-EARLY, a Phase III, multicenter, randomized, double-blind, parallel-group, active comparator controlled study. The study was designed to evaluate the safety and efficacy of upadacitinib monotherapy compared to methotrexate monotherapy in adult patients with moderate to severe rheumatoid arthritis who are methotrexate-naïve. In the first phase of the study, patients were randomized 1:1:1 to receive upadacitinib (15 mg or 30 mg, once-daily) or methotrexate. The study showed that both doses of upadacitinib monotherapy (15 mg and 30 mg) met the primary endpoints of ACR50 at week 12 and clinical remission at week 24 versus methotrexate (MTX). Additionally, all ranked secondary endpoints were met. Primary endpoints included ACR50 at week 12 and clinical remission at week 24 for upadacitinib versus methotrexate (superiority). All reported endpoints achieved p-values of <0.001 versus methotrexate for both doses through week 24, except for mTSS for the 15 mg upadacitinib dose at week 24 (p<0.01). At week 12, 76/77 percent of patients receiving 15/30 mg of upadacitinib, achieved ACR20, respectively, compared to 54 percent in the methotrexate group. At week 24, 79/60/44 percent of patients receiving the 15 mg dose of upadacitinib and 78/66/50 percent of patients receiving the 30 mg dose of upadacitinib achieved ACR20/50/70 response, compared to 59/33/18 percent of patients receiving methotrexate. In this study, the safety profile of upadacitinib was consistent with previously reported results from the other SELECT trials in rheumatoid arthritis.

**Viking Therapeutics Completes Enrollment in Phase II Study of VK2809**

Viking Therapeutics announced that enrollment has been completed in the company’s ongoing Phase II clinical trial of VK2809 in patients with primary hypercholesterolemia and non-alcoholic fatty liver disease (NAFLD). VK2809 is a novel, orally available small molecule thyroid receptor agonist that possesses selectivity for liver tissue, as well as the beta receptor subtype, suggesting promise in this patient population. The Phase II clinical trial is a randomized, double-blind, placebo-controlled, parallel-group study designed to evaluate the efficacy, safety and tolerability of VK2809 in patients with elevated LDL-cholesterol (LDL-C) and NAFLD. Patients have been randomized to receive once-daily oral doses of VK2809 or placebo for 12 weeks followed by a four-week off-drug phase. The trial’s primary endpoint will evaluate the effect of VK2809 treatment on LDL-C after 12 weeks compared to placebo. Secondary and exploratory endpoints include assessments of changes in liver fat content, triglycerides and other lipid markers. Patients experienced significant reductions in triglycerides, as well as the atherogenic proteins lipoprotein-a and apolipoprotein B. In a Phase Ib study in patients with mild hypercholesterolemia, treatment with VK2809 resulted in placebo-adjusted reductions in low-density lipoprotein ranging from 15 percent to 40 percent.

**SCYNEXIS Announces Phase I Study Results for SCY-078**

SCYNEXIS announced the results from a Phase I study of SCY-078, assessing the risk for drug-drug interactions when administered with drugs metabolized by the CYP family of enzymes. SCY-078 is currently in development for the treatment of fungal infections caused primarily by Candida. SCY-078 is the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids. SCY-078, the first representative of a novel oral and intravenous (IV) triterpenoid antifungal family, is in clinical development for the treatment of multiple serious fungal infections, including vulvovaginal candidiasis (VVC), invasive candidiasis (IC), invasive aspergillosis (IA) and refractory invasive fungal infections. In this open-label, two-period, crossover study, results demonstrated that co-administration of rosiglitazone with SCY-078 after repeat dosing had no clinically meaningful effect on rosiglitazone exposure compared with administration of rosiglitazone alone. SCY-078 was well absorbed following the loading dose, and repeated daily doses of rosiglitazone, in the presence and absence of repeat dosing of SCY-078, was generally well tolerated.
## Research Center Spotlight

Research Center Spotlight is a monthly selection of clinical research centers who have Research Center Profile pages posted on CenterWatch.com. Included in their annual subscriptions, company profiles are randomly selected to appear in this section, providing added exposure for their expertise and services in conducting and managing clinical studies.

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<tr>
<td>APG Research, LLC</td>
<td>Orlando, FL</td>
<td>(407) 423-7149 <a href="mailto:heidi@apghealth.com">heidi@apghealth.com</a></td>
<td>APG Research provides extensive service to Sponsors, physicians and research patients. Their team has a combined 40 years of clinical research experience in adult and pediatric studies including Addiction, ADHD, Anxiety, Autism, etc.</td>
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<tr>
<td>Cotton O’Neil Clinical Research Center</td>
<td>Topeka, KS</td>
<td>(785) 368-0741 <a href="mailto:mmartell@stormontvail.org">mmartell@stormontvail.org</a></td>
<td>Since 2004, the Cotton O’Neil Clinical Research Center has served as the research program of Stormont Vail Health. The Center is comprised of 29 clinical research professionals who partner with more than 50 organizational providers to provide access to clinical trials to patients.</td>
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<tr>
<td>Doctor’s Research Network</td>
<td>Miami, FL</td>
<td>(305) 662-1444 <a href="mailto:msurprenant@miamifoot.com">msurprenant@miamifoot.com</a></td>
<td>Doctor’s Research Network is a dedicated research center focusing mainly on lower extremity conditions. Their investigators have over 20 years of experience in conducting clinical trials. They have access to a large population of potential study subjects due to affiliations with multiple medical practices and clinics.</td>
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<tr>
<td>Manhattan Medical Research</td>
<td>New York, NY</td>
<td>(212) 480-3333 <a href="mailto:jckammd@att.net">jckammd@att.net</a></td>
<td>MMR is a multi-specialty medical research site proficient in Phase II-IV clinical trials. This new site expanded from University Urology Associates, which focuses mostly on urological studies. MMR will continue the tradition of UUA and expand the scope of research to target a wide range of therapeutic areas.</td>
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<td>(305) 722-7210 <a href="mailto:ofajardo@miamimedresearch.com">ofajardo@miamimedresearch.com</a></td>
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<td>Northern California Research</td>
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<td>(916) 484-0500 <a href="mailto:ljohnson@norcare.net">ljohnson@norcare.net</a></td>
<td>The mission of Northern California Research is to research, discover and apply knowledge to improve health, medical education and reduce illness.</td>
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<tr>
<td>Northern Pines Health Center, PC</td>
<td>Buckley, MI</td>
<td>(231) 269-4256 <a href="mailto:research@northernpineshealthcenter.com">research@northernpineshealthcenter.com</a></td>
<td>Northern Pines Health Center, PC is a private Family Practice office and Clinical Research Center conducting trials since 2006. The Research Division conducts Phase II-IV outpatient clinical trials.</td>
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<tr>
<td>Wright State University and Premier Health Clinical Trials Research Alliance</td>
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<td>Offers nimble, one-point-of-contact service for sponsors and a comprehensive, network-based solution and supports trials throughout a network of sites with comprehensive clinical trial assistance and infrastructure.</td>
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